



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0467]

Joint Meeting of the Blood Products Advisory Committee and the Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming joint public advisory committee meeting of the Blood Products Advisory Committee and the Microbiology Devices Panel of the Medical Devices Advisory Committee. The Committee will function as a medical device panel to provide advice and recommendations to the Agency on classification of devices. The Committee will also provide advice and recommendations to the FDA on research programs in the Office of Blood Research and Review. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on March 21, 2018, from 8 a.m. to 5:15 p.m. and March 22, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, sections B&C), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Bryan Emery or Joanne Lipkind, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, Bldg. 71, Rm. 6132, at 240-402-8054, bryan.emery@fda.hhs.gov and Rm. 6270 at 240-402-8106, joanne.lipkind@fda.hhs.gov respectively, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For those unable to attend in person, the meeting will also be available via webcast. The webcast will be available at the following link for both days: <https://collaboration.fda.gov/bpacmdac2018/>.

SUPPLEMENTARY INFORMATION:

Agenda: During the morning session on March 21, 2018, the Joint Committee will discuss and make recommendations regarding the device reclassification from Class III to Class II of nucleic acid and serology-based point-of-care and laboratory-based in vitro diagnostic devices indicated for use as aids in the diagnosis of human immunodeficiency virus (HIV) infection. In the afternoon session, the Committee will hear an overview of the research presentations on the research programs of the Laboratory of Emerging Pathogens, the Laboratory of Bacterial and Transmissible Spongiform Encephalopathy Agents, and the Laboratory of Molecular Virology in the Division of Emerging Transfusion-Transmitted Diseases, Office of Blood Research and Review Center for Biologics Evaluation and Research. After the open

session, the meeting will be closed to the public to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C 552b(c)(6).

On March 22, 2018, the Joint Committee will discuss and make recommendations regarding the reclassification from Class III to Class II of nucleic acid and serology-based in vitro diagnostic devices indicated for use as aids in diagnosis of hepatitis C virus (HCV) infection and/or for use as aids in the management of HCV infected patients.

All the devices that will be discussed by the Committee during the 2-day meeting are post-amendment devices that currently are classified into Class III under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 14, 2018. Oral presentations from the public will be scheduled between approximately 12:25 p.m. to 1:25 p.m. and from 4:25 p.m. to 4:40 p.m. on March 21, 2018, and between approximately 11:15 a.m. to 12:15 p.m. on March 22, 2018. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to

present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 6, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 7, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Bryan Emery at least 7 days in advance of the meeting (See, FOR FURTHER INFORMATION CONTACT).

Closed Committee Deliberations: On March 21, 2018, between 4:40 p.m. and 5:15 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the investigator's research will, along with other information, be used in making decisions regarding pay adjustments of service fellows or promotion of individual scientists who are permanent CBER staff.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.)

Dated: February 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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